

655 F.2d 236 (D.C. Cir. 1980). Since that time, substantial new evidence has become available to FDA. This evidence includes the emergence of a scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine and the disclosure of thousands of pages of internal tobacco company documents detailing that these products are intended by the manufacturers to affect the structure and function of the human body. This new evidence justifies the Agency's determination that cigarettes and smokeless tobacco are delivery systems for the drug nicotine.

Under the Act, a product is a drug or device if it is an article (other than food) "intended to affect the structure or any function of the body." Sections 201(g)(1)(C), 201(h)(3). The statutory definition is "intended to define 'drug' far more broadly than does the medical profession." *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793, 798 (1969). The legal question of whether cigarettes and smokeless tobacco are subject to FDA jurisdiction is one that "FDA has jurisdiction to decide with administrative finality." *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973).

After intensive investigation and careful consideration of the public comments, FDA concludes that cigarettes and smokeless tobacco meet the statutory definition of a drug and a device. This conclusion is based on two determinations: (1) nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body," and (2) these effects on the structure and function of the body are "intended" by the manufacturers.

The Agency's determination that nicotine in cigarettes and smokeless tobacco does

"affect the structure or any function of the body" is based on three central findings:

1. Nicotine in cigarettes and smokeless tobacco causes and sustains addiction.
2. Nicotine in cigarettes and smokeless tobacco causes other psychoactive (mood-altering) effects, including tranquilization and stimulation.
3. Nicotine in cigarettes and smokeless tobacco controls weight.

The Agency's determination that the manufacturers of cigarettes and smokeless tobacco "intend" these effects is based on five central findings:

1. The addictive and other pharmacological effects of nicotine are so widely known and accepted that it is foreseeable to a reasonable manufacturer that cigarettes and smokeless tobacco will cause addiction to nicotine and other significant pharmacological effects and will be used by consumers for pharmacological purposes, including sustaining their addiction to nicotine.
2. Consumers use cigarettes and smokeless tobacco predominantly for pharmacological purposes, including sustaining their addiction to nicotine, mood alteration, and weight loss.
3. Manufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine and mood alteration, and that consumers use their products primarily to obtain the pharmacological effects of nicotine.
4. Manufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of nicotine.
5. An inevitable consequence of the design of cigarettes and smokeless tobacco to provide consumers with a pharmacologically active dose of nicotine is to keep

consumers using cigarettes and smokeless tobacco by sustaining their addiction to nicotine.

This document is divided into six sections. Section I describes the evidence and legal basis supporting the Agency's finding that cigarettes and smokeless tobacco "affect the structure or any function of the body." Section II describes the evidence and legal basis supporting the Agency's finding that the manufacturers "intend" these effects on the structure and function of the body. Section III explains the Agency's conclusion that cigarettes and smokeless tobacco are combination products that contain a "drug" and a "device." Section IV explains why the Agency's decision to assert jurisdiction over cigarettes and smokeless tobacco is justified by the new evidence now available to the Agency. Section V demonstrates that Congress has not precluded or preempted the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco. Section VI addresses procedural issues relating to the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco. These sections are summarized below.

*I. Cigarettes and Smokeless Tobacco "Affect the Structure or any Function of the Body" Within the Meaning of the Act*

The nicotine delivered by cigarettes and smokeless tobacco has significant pharmacological effects on the structure and function of the body.

First, the nicotine in cigarettes and smokeless tobacco causes and sustains addiction. Nicotine exerts psychoactive, or mood-altering, effects on the brain that motivate repeated, compulsive use of the substance. These pharmacological effects create dependence in the user. The pharmacological processes that cause this addiction to nicotine are similar to those that cause addiction to heroin and cocaine.

Second, the nicotine in cigarettes and smokeless tobacco produces other important pharmacological effects on the central nervous system. Under some circumstances and doses, the nicotine has a sedating or tranquilizing effect on mood and brain activity. Under other circumstances and doses, the nicotine has a stimulant or arousal-inducing effect on mood and brain activity.

Third, the nicotine in cigarettes and smokeless tobacco affects body weight.

These effects on the structure and function of the body are significant and quintessentially drug-like. Moreover, these effects are the same as the effects of other drugs that FDA has traditionally regulated, including stimulants, tranquilizers, appetite suppressants, and products, such as methadone, used in the maintenance of addiction. For these reasons, the Agency finds that cigarettes and smokeless tobacco “affect the structure or any function of the body” within the meaning of the Act.

*II. Cigarettes and Smokeless Tobacco Are “Intended” to Affect the Structure and Function of the Body Within the Meaning of the Act*

To determine whether effects on the structure or function of the body are “intended” by the manufacturer, the Agency must objectively evaluate all the relevant evidence of intent in the record before it. “The FDA is not bound by the manufacturer’s subjective claims of intent,” but rather can find actual intent “on the basis of objective evidence.” *National Nutritional Foods Ass’n v. Matthews*, 557 F.2d 325, 334 (2d Cir. 1977). In the case of cigarettes and smokeless tobacco, the Agency finds that three types of objective evidence provide independent bases for finding that the manufacturers intend to affect the structure and function of the body: (1) the evidence of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco; (2) the evidence of

the actual consumer use of cigarettes and smokeless tobacco for pharmacological purposes; and (3) the evidence of the statements, research, and actions of the manufacturers themselves. Considered independently or cumulatively, this evidence convincingly demonstrates that cigarettes and smokeless tobacco are intended to be used for pharmacological purposes.

*A. A Reasonable Manufacturer Would Foresee that Tobacco Products Will Cause Addiction and Other Pharmacological Effects and Will Be Used by Consumers for Pharmacological Purposes*

When Congress enacted the current definition of “drug” in 1938, it was well understood that “[t]he law presumes that every man *intends* the legitimate consequences of his own acts.” *Agnew v. United States*, 165 U.S. 36, 53 (1897). Consistent with this common understanding, FDA’s regulations provide that a product’s intended pharmacological use may be established by evidence that the manufacturer “knows, or has knowledge of facts that would give him notice,” that the product is being widely used for a pharmacological purpose, even if the product is not being promoted for this purpose. 21 CFR 201.128, 801.4. Thus, FDA may find that a manufacturer intends its product to affect the structure or function of the body when it would be foreseeable to a reasonable manufacturer that the product will (1) affect the structure or function of the body and (2) be used by a substantial proportion of consumers to obtain these effects. For example, when it is foreseeable to a reasonable manufacturer that a product will produce drug effects in consumers and be purchased by a substantial proportion of consumers for drug purposes, FDA may consider the product a “drug.”

In the case of cigarettes and smokeless tobacco, no reasonable manufacturer could fail to foresee that these products will have significant pharmacological effects on consumers and be widely used by consumers for pharmacological purposes. All major public health organizations in the United States and abroad with expertise in tobacco or drug addiction now recognize that the nicotine delivered by cigarettes and smokeless tobacco is addictive. The first major organization to do so was the American Psychiatric Association, which in 1980 defined the “tobacco dependence disorder” and the “tobacco withdrawal syndrome.” Since 1980, nicotine in tobacco products has also been recognized as addictive by the U.S. Surgeon General (1986 and 1988), the American Psychological Association (1988), the Royal Society of Canada (1989), the World Health Organization (1992), the American Medical Association (1993), and the Medical Research Council in the United Kingdom (1994). Every expert medical organization that submitted comments to FDA on whether nicotine is addictive concluded that it is. The tobacco industry’s public position that nicotine is not addictive is simply not credible in light of this overwhelming scientific consensus.

The scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine makes it foreseeable to a reasonable manufacturer that these products will affect the structure and function of the body. This scientific consensus also makes it foreseeable that cigarettes and smokeless tobacco will be used by a substantial proportion of consumers for a pharmacological purpose—namely, to satisfy their addiction.

It is also foreseeable that the nicotine in cigarettes and smokeless tobacco will cause, and be used for, other significant pharmacological effects. It is well established that

the nicotine in cigarettes and smokeless tobacco has psychoactive or mood-altering effects in the brain. Under some circumstances, nicotine can have a sedative or tranquilizing effect on the brain; under other circumstances, nicotine can have a stimulating or arousal-inducing effect. In this regard, nicotine is similar to other addictive drugs such as opiates, which can have both stimulating and sedating effects. In addition, nicotine plays a role in weight regulation, with substantial evidence demonstrating that cigarette smoking leads to weight loss.

Because a reasonable manufacturer would foresee that cigarettes and smokeless tobacco will cause and be used for these well-established pharmacological effects in a substantial proportion of consumers, the Agency finds that these drug effects and drug uses are intended by the manufacturers.

*B. Consumers Use Tobacco Products to Obtain the Pharmacological Effects of Nicotine and to Satisfy Their Addiction*

A second basis for establishing that a product is intended to affect the structure or function of the body is evidence showing that consumers actually use the product for pharmacological purposes. In fact, courts have recognized that even in the absence of any other evidence of intent to affect the structure or function of the body, such an intent may be established by evidence showing that consumers use the product “predominantly” for pharmacological purposes. *ASH*, 655 F.2d at 239-240.

In the case of cigarettes and smokeless tobacco, the evidence establishes that consumers do use these products “predominantly” for pharmacological purposes. Major recent studies have concluded that 77% to 92% of smokers are addicted to nicotine in cigarettes. The U.S. Department of Health and Human Services estimates that 75% of

young regular users of smokeless tobacco are addicted to nicotine in these products. The comments from the American Heart Association, the American Lung Association, and the American Cancer Society, whose member physicians provide health care for tobacco users in the United States, confirm that “the vast majority of people who use nicotine containing cigarettes and smokeless tobacco do so to satisfy their craving for the pharmacological effects of nicotine; that is, to satisfy their drug dependence or addiction.”

In addition, a large proportion of consumers also use cigarettes and smokeless tobacco for other pharmacological purposes. A recent survey found that over 70% of young people 10 to 22 years old who are daily smokers reported that they use cigarettes for relaxation. The same survey found that over 50% of young people who are daily users of smokeless tobacco reported that they use smokeless tobacco for relaxation. Other surveys show that between one-third and one-half of young smokers report that weight control is a reason for their smoking.

This evidence that consumers actually use cigarettes and smokeless tobacco predominantly to obtain the pharmacological effects of nicotine leads FDA to find that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

*C. The Statements, Research, and Actions of the Cigarette Manufacturers Show that the Manufacturers Intend to Affect the Structure and Function of the Body*

A third basis for establishing that a manufacturer intends to affect the structure or function of the body is evidence from the statements, research, and actions of the manufacturer that reveals that the manufacturer knows that its product will, or designs its

product to, affect the structure or function of the body. It is a canon of statutory construction that words used by Congress should ordinarily be interpreted in accordance with their plain meaning. The plain meaning of “intend” includes “to have in mind” or “to design” for a particular use. The *American Heritage Dictionary*, for instance, defines “intend” as: “1. To have in mind; plan. 2.a. To design for a specific purpose. b. To have in mind for a particular use.” Consistent with the plain meaning of “intend,” FDA may consider whether the statements, research, and actions of the manufacturer show that the manufacturer “has in mind” that its product will, or “designs” its product to, affect the structure or function of the body.

The administrative record contains three decades of documents and other evidence from the major cigarette manufacturers. This evidence, most of which has only recently become available, establishes that the manufacturers do “have in mind” that their products will have and be used for pharmacological effects. First, the evidence shows that the cigarette manufacturers know that nicotine is a pharmacologically active drug. In internal documents, for instance, researchers for Philip Morris Inc. call nicotine “a powerful pharmacological agent with multiple sites of action” and “a physiologically active . . . substance . . . [which] alters the state of the smoker by becoming a neurotransmitter and a stimulant”; a researcher for R.J. Reynolds Tobacco Co. (RJR) calls nicotine “a potent drug with a variety of physiological effects”; and researchers for Brown & Williamson Tobacco Corp. and its parent company, BAT Industries PLC (formerly the British-American Tobacco Co.) (BATCO), call nicotine “pharmacologically active in the brain”

and “an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical, and physiological responses.”

Second, the evidence establishes that the cigarette manufacturers have conducted extensive research to understand precisely how nicotine affects the structure and function of the body. In one year alone, Philip Morris conducted 16 different studies on the effects of nicotine, including 5 experiments to determine the pharmacological effects of nicotine on the human brain. RJR’s similarly extensive research found that the nicotine in cigarettes produces measurable changes in brain wave activity, such as “a significant increase in beta2 magnitude” (an effect associated with anxiety relief) and “a significant decrease in delta magnitude” (an effect associated with improved mental condition). Through the Council for Tobacco Research, an organization formed by the major tobacco companies, the manufacturers funded dozens of sophisticated investigations concerning nicotine, including numerous studies that demonstrate nicotine’s ability to alter the function of the human brain.

Third, the evidence shows that the manufacturers know that one of the pharmacological effects of nicotine is to cause and sustain addiction. Researchers and senior officials of Brown & Williamson and BATCO expressly acknowledge this fact in their internal documents, stating that “smoking is a habit of addiction” and that “nicotine is addictive.” Philip Morris scientists also know of nicotine’s addiction potential. They conducted a series of nicotine “self-administration” experiments using the tests used by the National Institute on Drug Abuse to determine whether a substance has addiction potential. These studies found that rats would self-administer nicotine, which is one of the